

**MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL - DIVISION OF FAMILY
HEALTH
MAINE BIRTH DEFECTS PROGRAM**

CHAPTER 280

RULES RELATING TO THE MAINE BIRTH DEFECTS PROGRAM

SUMMARY:

These rules establish the responsibilities of hospital administrators, physicians and other health care providers with regard to the reporting of the presence of birth defects in infants and fetuses; the confidentiality requirements of the Maine Birth Defects Program; the nature of contact between the Maine Birth Defects Program and families of children with birth defects, and the provision for parental objection to birth defect reporting or participation in the birth defect registry.

1.0 PURPOSE

These rules implement the Maine Birth Defects Program, as established pursuant to Title 22, Chapter 1687 of the Maine Revised Statutes.

2.0 DEFINITIONS

2.1 “Birth hospital” means any hospital licensed under the provisions of Title 22 of the Maine Revised Statutes which provides health care services to pregnant woman and those who give birth.

2.2 “Birthing center” means any non-hospital health facility, institution, or place designed to accommodate mothers giving birth away from home at the culmination of normal, uncomplicated pregnancies.

2.2 “Birth defect” means a major structural abnormality which impacts upon a fetus, newborn or infant’s ability to function or survive. For reporting purposes, only those birth defects included in the Appendix to these rules need be reported.

2.3 “Reportable birth defects” means those birth defects which hospitals, physicians and other health care providers licensed under the provisions of Title 22 or Title 32 of the Maine Revised Statutes are required to report. These reportable birth defects are identified in the Appendix to these rules.

2.4 “Specialty provider” means those licensed under Title 32 who have additional certification by or eligibility for one of the disciplines of the American boards of certification and is registered and certified by the appropriate specialty boards.

3.0 RESPONSIBILITY FOR REPORTING

3.1 The administrator of the hospital and/or those professionals licensed pursuant to Title 32 engaged by a birthing center are responsible to report to the Maine Birth Defects Program("Program"), using forms provided by the Department, in the event of a diagnosis of a reportable birth defect involving any fetus or infant born in this state to a Maine resident. This reporting requirement extends to any live born or stillborn infant diagnosed at birth or to any infant one year of age or younger admitted to the hospital or outpatient office/clinic for diagnosis or treatment related to a reportable birth defect.

3.2 Each administrator of a hospital subject to licensing requirements established under either Title 22 or Title 32, which provides health care for pregnant woman or for infants, shall designate a contact person responsible for coordinating the reporting of birth defects by the facility to the Maine Birth Defects Program. Such designee should be a clinical person with appropriate experience in either obstetrics or newborn care, unless the Birth Defects Program authorizes another designee. Each such administrator shall advise the Birth Defects Program of the identity of the contact person for his or her facility.

3.3 The designated contact person shall also be responsible for the submission of appropriate reports to the Maine Birth Defects Program regarding any infant or fetus diagnosed with a reportable birth defect.

3.4 The administrator of any hospital licensed pursuant to Title 22 of the Maine Revised Statutes shall also designate a contact person within the Medical Records Department to coordinate the provision of all relevant medical records and other information pertaining to an infant or fetus diagnosed with a reportable birth defect to the Maine Birth Defects Program. The administrator shall also furnish the name of such contact person to the Program.

3.5 Each hospital or birthing center subject to these Rules will be provided a report form by the Birth Defects Program, which will identify the required reporting data pertaining to the mother and infant/fetus, along with a listing of reportable birth defects under these Rules.

3.6 The administrator of each hospital or licensed professionals engaged by a birthing center subject to these Rules is responsible for assuring that all facility staff, with responsibility for obstetrical or newborn care, are informed of their respective responsibilities under these Rules.

4.0 RESPONSIBILITY OF THOSE PROVIDING PEDIATRIC SERVICES

4.1 Any primary care physician, specialty physician or other health care provider licensed pursuant to Title 32 of the Maine Revised Statutes who diagnoses a reportable birth defect in a newborn or infant in the first year of life shall report to the Maine Birth Defects Program such birth defect. The physician or other health care provider shall report on a form provided by the Birth Defects Program, if possible.

4.2 The reporting requirements under this subsection extend to the presence of a birth defect in any fetus, newborn or infant delivered by Maine residents.

5.0 RESPONSIBILITY OF THOSE PROVIDING OBSTETRICAL SERVICES

5.1 Any physician or other health care provider licensed pursuant to Title 32 of the Maine Revised Statutes who diagnose a fetus with a reportable birth defect shall submit a report regarding the birth defect to the Maine Birth Defects Program, regardless of the outcome of the pregnancy.

5.2 In the event the subject pregnancy results in other than a live birth, any such physician or other health care provider who provides care to the mother shall submit to the Birth Defects Program a report confirming the presence of a birth defect in the fetus or stillborn.

6.0 TIMING OF REPORTING THE PRESENCE OF A BIRTH DEFECT IN AN INFANT OR FETUS

6.1 The required report is to be submitted to the Maine Birth Defects Program, either within 24 hours of the time the infant is discharged or transferred, or within 7 days of the diagnosis of a reportable birth defect, whichever occurs first.

6.2 Diagnosis of a birth defect in a fetal death shall be reported within 7 days of the diagnoses or confirmation of a reportable birth defect.

7.0 CONFIDENTIALITY OF ALL REPORTING DATA

7.1 All data reported to the Maine Birth Defects Program, which contains either direct or indirect individually identifiable information, shall be confidential.

7.2 Information submitted to the Birth Defects Program shall only be available to qualified organizations with a documented history of scientific research or other researchers determined to be appropriate by the Program. In any event, disclosure of any individually identifiable information will be in conformity with applicable state and federal law.

7.3 Any organization or individual which requests individually identifiable information from the Birth Defects Program may be required to execute such confidentiality agreements as the Program deems appropriate.

7.4 Institutional Review Board approval is required for any research plan which involves either the use or release of any information contained in the Birth Defects Program. Any such Institutional Review Board must be established in conformity with applicable regulations established by the U.S. Department of Health and Human Services including but not limited to *45 CFR, Subtitle A, Part 46, §§ 46.101-46.409. (Revised as of Oct. 1, 2002).*

7.5 In the event a proposed research plan involves contacting family members, written consent of the parent or guardian of any infant or fetus will be required as a predicate for use or release of any information from the Birth Defects Program.

8.0 CONTACT WITH FAMILIES

8.1 The Birth Defects Program may contact families to provide information about available services.

8.2 Referrals shall be made to the Department of Health and Human Services, Children with Special Health Needs Program and/or Public Health Nursing to provide information on available services. Other referrals will be made upon the request of the parent or guardian of an infant, newborn or fetus.

8.3 No family will be required to accept any services offered by the Birth Defects Program, including any nursing visit or referral.

8.4 In the event of a prenatal diagnosis of a reportable birth defect, the Birth Defects Program will not contact the family, unless requested to do so by the family or physician or other health care provider subject to these Rules.

9.0 PARENTAL OBJECTION TO PARTICIPATION

9.1 In the event of parental objection on the basis of sincerely held religious beliefs, neither the hospital, birthing center, or health care provider subject to these Rules may be required to report the presence of any birth defect.

9.2 Parental objection to reporting and participation in the Birth Defects Program based on sincerely held religious beliefs shall be clearly documented in writing, and incorporated into the medical records of the mother, infant and newborn.

9.3 In the event of documented parental objection to participation in the Birth Defects Program, based upon sincerely held religious beliefs, the Program shall not collect or gather any medical records relating to birth defects of the fetus, newborn or infant.

APPENDIX

Reportable Birth Defects:

Spina Bifida

Anencephaly

Encephalocele

Cleft Lip and/or Palate

Trisomy 21

Gastroschisis

Omphalocele

Hypospadias

Upper Limb Deformities

Lower Limb Deformities

Major Cardiac Defects:

Coarctation of Aorta

Double Outlet Right Ventricle

Hypoplastic Left Heart

Interrupted Aortic Arch

Pulmonary Atresia with intact ventricular septum

Single Ventricle

Tetralogy of Fallot

Tricuspid Atresia

Transposition of the Great Vessels

Truncus Arteriosus

Basis Statement: These Rules are adopted to define responsibilities related to the reporting of the presence of birth defects in infants and fetuses unless the infants' parents object due to sincerely held religious beliefs and to the confidentiality requirements of the Maine Birth Defects Program. These Rules assure complete and accurate information is available to the Program to identify birth defects; their causes, risk factors and strategies for prevention and the provision of services.

Effective Date May 17, 2008